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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/057,431

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Peter Paasch Mortensen

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NOVOZYMES NORTH AMERICA, INC.  
500 FIFTH AVENUE  
SUITE 1600  
NEW YORK, NY 10110

EXAMINER

DEJONG, ERIC S

ART UNIT

PAPER NUMBER

1631

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/057,431	<b>Applicant(s)</b> MORTENSEN, PETER PAASCH	
	<b>Examiner</b> ERIC S. DEJONG	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-20, 28, 44 and 47-56 is/are pending in the application.
- 4a) Of the above claim(s) 28, 50 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-20, 44, 47-49 and 52-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/21/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED OFFICE ACTION**

Applicants response filed 08/07/2008 is acknowledged.

Claims 13, 21-27, 29-43, 45, and 46 are canceled. Claims 28, 50, and 51 are withdrawn. Claims 54-56 are newly presented. Claims 1-12, 14-20, 44, 47-49, and 52-56 are currently under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 02/21/2008 is acknowledged. However, the foreign documents cited therein have not been considered but a copy of said foreign documents have not been provided by applicants.

### ***Claim Rejections - 35 USC § 102***

The rejection of claims 1-12, 14-20, 44, 47, and 48 under 35 U.S.C. 102(e)(2) as being anticipated by Chandler et al. (US Patent No. 6,268,222) is withdrawn in view of amendments made to the instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 14-20, 44, 47-49, and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler et al. (US Patent No. 6,268,222). This rejection is necessitated by amendments made to the instant claims.

The instant claims are drawn to a method of fluorescence analysis comprising illuminating a granular composition comprising a purified biologically active compound containing a fluorescent marker, detecting light emitted from the fluorescent marker, and predicting the amount of fluorescent marker in the granular composition. The prediction of the amount of fluorescent marker in the granular composition is accomplished by comparing the light emitted therefrom to data on light emitted from a known granular composition. Further, amendments made to the instant claims are directed toward the fluorescent product which is analyzed, and does not further involve or add additional steps to the recited process.

Chandler et al. sets forth the development and applications of novel fluorescent articles comprising a core particle region having on its surface a plurality of smaller polymeric particles stained with different fluorescent dyes (see Chandler et al., Abstract and throughout), which reads on a first and second granular composition comprising a core and a layer capable of fluorescence emission as recited in claim 1. Chandler et al.

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further discloses methods for detecting multiple subpopulations of analytes of interest employing a fluorescent, complementary binding moiety to each of said analytes, wherein each analyte and its complementary binding moiety comprise first and second members of a specific binding pair (see Chandler et al., col. 15, line 38 through col. 16, line 44). The disclosed method includes the steps of forming a mixture of the fluorescently labeled moieties of the binding pair, contacting the mixture and a solid support so that specific binding pairs are formed on solid supports, and relating the presence and concentrations of the analytes of interest in the sample by means of observing and quantifying a resultant fluorescence signal (see Chandler et al., col. 4, line 51 through col. 5, line 42 and Examples 1-11 at col. 16, line 55 through col. 24, line 53), which reads on detecting and obtaining data on emitted light from a first and second granular composition as recited in claim 1. Further, Examples 1 and 3 of Chandler et al. further sets forth an embodiment of the disclosed invention wherein different microparticle samples were stained with a predetermined amount of different fluorescent dyes, which reads on a first granular composition having known quality parameters as recited in claim 1. The different microparticle samples were further mixed together at different ratios to form a new series of samples, which reads on a second granular composition as recited in claim 1 and. Treating this ratio as an unknown, Chandler et al. sets forth the empirical determination of the ratio of different microparticles based on the comparison to known data regarding the relationship between a particular microparticle concentration and the fluorescence intensity of the specific fluorescent dye used to stain each original collection of microparticles, which

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reads on predicting the amount of fluorescent marker of the second granular composition as recited in claim 1, a prediction including comparing light from a second composition to that of the first known composition as recited in claim 10, and a prediction made in real time as recited in claim 11. The fluorescence intensity measured from each of the new series of samples allowed for the determination and back calculation of the particular ratio of different microparticles. Therefore, Chandler et al. further anticipates the method of claim 44 in the above example by demonstration of a calibration model from granular compositions of known quality that, by comparative means, are used to evaluate the quality of samples of unknown quality.

The disclosed fluorescent particles range from 0.1 to 1,000  $\mu\text{M}$  in diameter (see Chandler et al., col. 3, lines 9-20), which reads on a first and second granular composition having an average size between 20-2000  $\mu\text{M}$  as recited in claim 20. Chandler et al. further discloses that the composition of the particles may comprise cross-linking agents allowing for the coupling of reactive surfactant agents and to biological materials including enzymes (see Chandler et al., col. 12, lines 58-64) that allow for interaction with and, subsequently, the detection of antigens, proteins, enzymes, and other biological molecules (see Chandler et al., col. 3, lines 56-62 and col. 4, lines 45-50), which reads on granular compositions comprising a purified enzyme as recited in claim 1, a homogenous substantially continuous layer of purified enzyme disposed on a core as recited in claims 19 and 47, an enzyme bio-catalyst or therapeutic agent as recited in claim 12, and granular compositions that further comprise auxiliary granulation agents as recited in claims 15-18. Further, Example 11 of

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Chandler et al. teaches specific embodiments of enzymes for use with the disclosed micro/nanoparticles that are hydrolases and oxidoreductases, which reads on the enzyme is a hydrolase or oxidoreductase as recited in claim 14. The fluorescent particles are further disclosed as being capable of emitting a single fluorescence emission or multiple fluorescence emissions with emission spectra ranging from 450 nm to 1000 nm (see Chandler et al., col. 4, lines 15-30), which reads on the emitted light of 1-10 discrete monochromatic wavelengths as recited in claim 5 and 6. Further, fluorophores that emit light at and above 450 nm are inherently excited to fluoresce by sources of ultraviolet light in the range of 10-350 nm as recited in claims 2-4. The detection means disclosed for observing and measuring fluorescence emissions includes, digital cameras (CCD) as well as other means for converting observed light into digital signals and two-dimensional images (see Chandler et al., col. 4, line 59 through col. 5, line 4), which reads on the at least one detector and at least two detectors as set forth in claims 7-9 and converting emitted light into an electronic signal as recited in claims 44 and 48.

Chandler et al. does not expressly teach the specific layered structure of particles as instantly claimed. However, one of skill in the art would recognize that the use of known prior art processes used in fluorescence analysis and for quality parameter measurements on suitable, alternative fluorescent particles, such as that instantly claimed, would produce only the expected results. Well known fluorescent measurement processes would be expected to produce predictable results as such processes encompass only routine experimentation. Therefore, the instantly claimed

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process is not differentiated from that of the prior art as there is no evidence of record that demonstrates any unpredictable result that results from using fluorescent particles such as that instantly claimed.

### ***Response to Arguments***

Applicant's arguments filed 08/07/2008 have been fully considered but are moot in view of the new grounds of rejection set forth above.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S DeJong/  
Examiner, Art Unit 1631